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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,145	01/30/2001	Eilaz Babaev	24149.14	1226

7590

04/27/2004

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT	PAPER NUMBER
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3737

13

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,145

Applicant(s)

BABAEV, EILAZ

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/24/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,9-11 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,9-11 and 19-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 11/24/03 have been fully considered but they are not persuasive.

Regarding the Carter and Briskin references, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., creation of ultrasound standing waves through air/tissue as opposed to *inside* a catheter/blood vessel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner maintains that the distal radiation surface of Carter is with respect to the ultrasound transducer (24) and further points out that applicant's specification admits that "standing waves are more effective in limited space or area as a tube" (see p. 3 lines 11 and 12 and p. 5 line 22). The examiner also maintains that treatment of a wound encompasses disruption of blood clots as further supported by the specification of the present invention p. 6 lines 1-4.

Regarding the Martin et al. reference, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an exteriorly located wound surface) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's arguments/amendments filed 11/24/03 have overcome the previous rejections under 35 USC § 112.

Claim Interpretation

It is understood from the specification that standing waves occur as a result of (constructive) superposition of incident and reflected ultrasound waves, wherein the distance of occurrence is inherently defined as $n \times \lambda/2$ (page 3, first paragraph).

Since the specification does not indicate otherwise, the examiner assumes for examination purposes that bactericidal/therapeutic/decreased healing time- effects are intrinsic properties of standing waves/radiation pressure applied to a wound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 9-11, 22, 23, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter '663.

Carter teaches a method and apparatus for adjustably creating standing waves traveling from a distal radiation surface of an ultrasound transducer (24) through a guide, or bushing, (44) to a surface of a wound for treatment. See figures 4a and b, col. 2 lines 13-25. Carter further teaches ultrasound frequencies between 50kHz-1.3MHz (col. 6 lines 21-27).

3. Claims 1, 2, 9, 10, 19-23, 25 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. '499 of record

Martin teaches a method and apparatus for treating a wound using focused ultrasound by adjusting the position of a transducer to achieve superposition of incident and reflected waves (i.e., standing waves) at the surface of the wound/target region. See fig. 4B, 6A-C, 11 and 12 and col. 10 lines 22-45. Martin further teaches wherein the ultrasound frequency is 0.5-20MHz and wherein continuous or pulsed energy may be used (col. 9 lines 15-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter or Martin et al. '499 of record.

Regarding claims 3 and 24, Carter and Martin et al. do not explicitly address a distance of at least 0.1", however lacking any criticality, the distance of the created standing waves would have been an obvious matter of design choice to a person of ordinary skill in the art depending upon the particular application.

5. Claims 20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter '663.

Regarding claims 20 and 25, Carter does not address the applied waveform explicitly, however lacking any criticality, the shape of the waveform would have been an obvious matter of design choice to a person of ordinary skill in the art depending upon the particular application.

6. Claims 6 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter in view of Brisken '811 of record.

Regarding claims 6 and 27, Carter differs from the claimed invention in that a drug is not explicitly addressed. Brisken teaches a method and apparatus for enhanced fluid/drug delivery in the removal of intravascular plaque and clots using ultrasound standing waves. See col. 1 lines 57-62 and col. 12 lines 9-28. It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to use a drug such as a thrombolytic agent as taught by Brisken in the invention as taught by Carter to enhance intravascular clot dissolution.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Petty (6,314,318) teaches a known method and device for treating infection using standing radio frequency waves.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

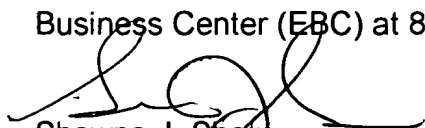
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
4/20/04